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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/783,633

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Steven R. Bailey

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

NOTIFICATION DATE

DELIVERY MODE

03/25/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

scotugno@biopatentlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/783,633	<b>Applicant(s)</b> BAILEY ET AL.	
	<b>Examiner</b> CHERYL MILLER	<b>Art Unit</b> 3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 68,69,71-78 and 80-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68,69,71-78 and 80-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/8/2010</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 68-85 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 68, 69, and 71-76 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Freitag (US 5,601,593). Freitag discloses a sensor device (stent 1, see fig.1 or fig.2) comprising a plurality of structural elements (3, 4, 6-9), the elements including a first region (3 or 6) of a first material having a transitional temperature and coefficient to expand from a first to a second state (col.4, lines 20-22, 30-33), the elements including a second region (4 or 7) of a second material having a higher transitional temperature and coefficient (col.4, lines 22-24, 34-39) which allow for a change in geometry of the second region in the second state upon application of a force to the sensor device, wherein the change in geometry changes the positioning of the second region (4) relative the first region (3) during the higher transition temperature (application of heat to above 40C), the first and second materials being shape memory or superelastic (nitinol, col.4, lines 20-25). Freitag discloses sensor

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device's (stents) are typically implanted endoscopically (col.1, lines 15-20; endoscopes have optical abilities to view proper positioning of the stents in the vessel thus may be considered the detection mechanism). If not inherent that an endoscope (detection mechanism) is present, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the stent with an endoscope to ensure the stent is positioned at the correct location in the vessel needing treatment and ensuring proper expansion has taken place. The superelastic and shape memory materials used by Freitag are responsive to temperature, flow rate and plaque buildup as the material may move elastically by the pumping of blood and force by tissue buildup or tissue attachment to the stent surface.

Claims 68-69 and 71-76 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tu et al (US 6,406,493 B1). Tu discloses a sensor device (annuloplasty stent, see fig.1; col.4 line 66-col.5 line 2) comprising a plurality of structural elements (11, 13a-b, 14a-b), the elements including a first region (13) of a first material having a transitional temperature and coefficient to expand from a first to a second state (col.6, lines 42-53), the elements including a second region (14) of a second material having a higher transitional temperature and coefficient (col.6, lines 54-65) which allow for a change in geometry of the second region in the second state upon application of a force (temperature forces open) to the sensor device, wherein the change in geometry changes the positioning of the second region (14) relative the first region (13) during the higher transition temperature (col.6, lines 54-65), the first and second materials being shape memory or superelastic (col.6, lines 9-29). Tu discloses the sensor device (annuloplasty stent) to be used with RF energy, IR energy, ultrasound, laser, catheter, fiber optics, etc, which typically include imaging means that may be

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considered the detection mechanism as the application of heat/energy need be correctly positioned within the stent in order to assume proper positioning and expansion. If not inherent that the disclosed heat applicators contain imaging capabilities (detection mechanism), it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the annuloplasty stent with an imaging means to ensure the annuloplasty stent is positioned at the correct location in the vessel needing treatment and ensuring proper expansion has taken place. The superelastic and shape memory materials used by Tu are responsive to temperature, flow rate and plaque build up as the material may move elastically by the pumping of blood and force by tissue buildup or tissue attachment to the stent surface.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 77-78 and 80-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orth et al. (US 5,591,197) in view of Flomenblit et al. (US 5,562,641). Orth discloses a sensor device (stent, see fig.5) comprising a plurality of structural elements (13, 16, 20), the elements including a first region (13) of a first material that expands from a diameter to a second diameter, the elements including a second region (20) of a second material which allow for a change in geometry of the second region, wherein the change in geometry changes the positioning of the second region (20) relative the first region (13), the first and second materials being shape memory or superelastic (col.9, lines 30-32). Orth discloses using typical intraluminal delivery

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systems using guidewires with typically include imaging means that may be considered the detection mechanism as the imaging need be present to correctly position the stent in the treatment location of the vessel. If not inherent that the disclosed delivery devices contain imaging capabilities (detection mechanism), it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the stent with an imaging means to ensure the stent is properly positioned and expanded. Orth discloses the stent to be made of superelastic or shape memory materials (col.9, lines 29-31), the first and second regions (13 and 20) possibly being made of different materials (col.10, lines 39-42), and expanding at different times (fig.5, 6 and corresponding description; uses force by balloon or other means to move the second region instead of temperature) however is silent to mention the different regions to have different transition temperatures/coefficients. Flomenblit teaches in the same field of stents, the use of different transitional temperatures/coefficients at different regions of the stent for better control over the positioning of the stent in the vessel (can control portion by portion; col.6, lines 13-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Orth's piecewise stent (having first and second regions that expand at different times independently) with Flomenblit's teaching of using two different transitional temperatures to expand different portions of a stent at different times, in order to provide a stent with increased control over individual regions during implantation. Orth's second elements (20) would have a first coplanar position after the first elements (13) radially expand and a second projecting position after elements 20 expand.

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The superelastic and shape memory materials used by Orth are responsive to temperature, flow rate and plaque build up as the material may move elastically by the pumping of blood and force by tissue buildup or tissue attachment to the stent surface.

Claims 77-78 and 80-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freitag (US 5,601,593) in view of Pollock et al. (US 2007/0255395 A1). Freitag discloses a sensor device (stent, see fig.1, 2 having first elements 3, 6 and second elements 4, 7 with different transitional temperatures), see above. Freitag does not however disclose barbs/hooks on the stent. Pollock teaches in the same field of stents, the use of barbs/hooks (20) on the ends of stents (may be applied to any stent configuration (P0031, P0032) in order to attach the stent to the vessel wall (P0006). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Freitag's stent with Pollack's teaching of barbs on the ends of the stent in order to provide a stent with barbs for better securement to the vessel wall. Such a stent meets the limitation of second elements (4, 7-which include barbs) having a higher transitional temperature/coefficient in a first position is substantially coplanar with the first elements (fig.3 of Pollack, P0028, capable of deforming to coplanar configuration) and a second position projection outwardly from the first elements (barbs 20 project outward to penetrate the vessel, see fig.1, 2).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/Cheryl Miller/

Examiner, Art Unit 3738

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738